Before discussing the rejections under 35 U.S.C. §§102 and 103, Applicant wishes to review the advantages of the present invention and the features thereof that confer these advantages.

As discussed at length in the Specification, the present invention is directed to a prosthetic system or device for the replacement of damaged knee joints, that is able to accomodate either partial or total joint replacement. Specifically, the articular surfaces and structures of the knee are often damaged either by external trauma or by disease, and are so compromised in their condition that replacement is necessary. Different levels of injury require correspondingly different treatment. For example, damage to the articular surfaces of the adjacent bones, the femur and the tibia, may require the replacement of these surfaces only, while the surrounding ligamenture may be retained. Correspondingly, and particularly in the instance of external trauma such as traffic or sports injuries, the surrounding tissue may likewise be irreparably damaged or destroyed, and in such intance, a total prosthesis is required.

Classically, the prostheses utilized for total replacement have operated ostensibly on the concept of a single-axis construction, with the exception of the device of Walker, applied by the Examiner, which however, offers flexion in the vertical plane of the knee joint, and as discussed below, fails to appreciate the goals and features of the present invention. Such devices have provided patients with limited joint rotation and limb movement, and have not been able to restore normal limb motion. A detailed exposition of the extant prior art in this area is set forth in the Specification at pages 12 and 13.

One of the observations underlying the present invention, is that knee joint movement is not merely the rotation of the tibia about an axis associated with the femur, but the sliding movement or translation of the adjacent articular surfaces in contact with each other to maintain maximal surface contact and consequent support and natural movement. Particularly, the applicant has observed that the devices extant in the art have generally failed to effectively accomodate the temporal occurrence and actual character of posterior roll-back, or the translation of the femoral articular surface with respect to the adjacent tibial surface, that takes place in the normal knee joint during flexion. In this connection, the Examiner is referred to the Specification at page 10, lines 15-25. This is particularly important in the instance of a total knee replacement where the posterior cruciate ligamenture is removed and there is no posterior stabilization apart from that conferred by the design of the prosthesis.

Accordingly, it is the rolling and sliding contact between the respective articular surfaces of the femur and tibia in conjunction with their translational movement with respect to each other, all during the movement of the knee joint, that has been lacking in the performance of the prostheses of the prior art and that has been achieved in the construction of the present invention. This is particularly evident in the embodiment of the invention that is under prosecution herein, that relates to the provision of a hinged prosthesis. The broader concept of the invention, set forth and prosecuted in Applicant's parent application, has been awarded U.S. Patent No. 5,358,527, issued October 25, 1994, against the same prior under consideration herein. The features of the invention

are submitted to be all the more surprising and distinctive, it is submitted, when it is considered that they are attained in a hinged construction.

To summarize, the present invention proposes to address the need for a device that will at once, impart a range of action and movement to the patient that fully replicates the natural action and capability of the original knee joint, and that will do so whether it is installed in full replacement of the natural knee joint and all of its attending ligamenture, or whether it will reside in cooperative relationship with retained ligamenture such as a retained or resected posterior cruciate ligament. Significantly, the present structure imparts motion corresponding to that capable by original joint tissue, such deceleration and translational motion. These capabilities have heretofore been incapable of natural replication, as the constructions extant in the prior art are developed around a single hinge principle.

Turning to the claims, Claims 41 and 51 have been amended to further emphasize the salient features of the prosthesis and the hinge component, that they provide a variable axis construction that facilitates and demonstrates by their operation, both translational movement and rolling and sliding contact that simulate natural knee mechanics. As will be discussed in detail below, none of the prior art of record either suggests or achieves these objectives and features. Having the above in mind, a review of the rejections of record proceeds below.

Claims 41-43, 45, 48, 50-54 and 57 have been rejected under 35 U.S.C. §102(b) as anticipated by Forte et al. ('041). As this rejection may pertain to the claims, particularly as amended, it is traversed.

The citation of Applicant's earlier patent against the present invention prompted the review and restatement of the essence of the present invention as set forth above, so as to make clear the profound differences in function and consequent structure of this prosthetic construction. In this connection, the Examiner focuses on the disclosure of Forte et al. '021, which is concerned with a posteriorly-stabilized total knee prosthesis, and particularly, Figures 14-20, for what are considered to be teachings corresponding to the present invention.

Particularly, Figures 14-20 of Forte et al. '021 depict a <u>single</u> <u>axis</u> hinged knee prosthesis as discussed and distinguished earlier herein. Firstly, the concave rails 88 cited are germane only to the patella-femoral joint and are located on the medial and lateral inside corners of the condyle portions of the femoral component 10. Rails 88 contact the bearing surface portions 94 of patella component 80, during knee flexion. The patella-femoral bearing surface mechanics, as presented, purports to increase surface contact area during knee flexion and has nothing to do with the femoro-tibial biomechanics such as femoral roll-back, posterior stabilization, and maintenance of the femoro-tibial joint forces and flexion mechanics of the knee prosthesis.

Surface 130 is referred to by the Examiner as "convex cam member surfaces", portion 142 is referred to as "concave cam member surfaces", element 122 as "multi-radius tibial plateau bearing surface means", and surfaces 132 and 144 as "follower member means." The implication of this nomenclature appears to be to demonstrate that the present invention is fully disclosed in Forte et al. '021 by attempting to identify design similarity of various components. However, this is not the case.

The various surfaces referenced by the Examiner are not cam members at all, but are part of the femoro-tibial bearing surface means. The femoro-tibial bearing contact surfaces in Forte et al. '021 have a fixed center of rotation and consist of outer surface portion 134 of hinge pin 116 with inner surface portion of bearings 114 and femoral condyle bearing portions 130 with posterior tibial bearing portions 132. These bearing surfaces sustain the femoro-tibial joint forces during flexion-extension of the knee joint and function as stationary-sliding bearings; since they articulate relative to a fixed center of rotation. The characteristic mode of bearing articulation, therefore, does not allow the femoral component 10 to translate anteriorly-posteriorly, relative to the tibial component 60 - like the natural like multi-axis biomechanics of the present invention.

Surfaces 122 comprise the inside walls of slot 120 and are apposed adjacent to femoral rails 88, during the early stages of flexion; hence, are intended to sustain side-loading. Surfaces 142 on femoral component 10 only comes into contact with the anterior tibial surfaces 144 during the initial stage of flexion (and the final stage of extension) and hence, functions as a "bumper" surface to dissipate impact loading - usually associated with conventional hinged knee prosthesis, due to a reduced soft tissue deceleration capability from compromised/absent adjacent soft tissue structures.

The Examiner also contends that Figure 15 depicts surfaces on hinge post 106 and on femoral component 10, including sliding lateral surfaces that engage each other in rolling and a sliding contact when the joint nears full extension. This interpretation of the reference is incorrect. Firstly, no surface portion of hinge post 106 functions as an articular bearing surface. It solely functions to maintain the femoro-tibial flexion axis in

a fixed pivot position by retaining the assembled bearings 114 within the transverse through hole 112. The lateral surfaces of the hinge post (not identified) do not come into contact with the inner lateral femoral surfaces (not identified), adjacent to the concave rails 88 of femoral component 10. In fact a side clearance space exists, which essentially equals the thickness of the lateral outer shoulder portion (not identified) of bearings 114. If surface contact did exist, between the hinge post 106 and adjacent surfaces, the resulting bearing couple would be metal-to-metal; which, for joint implant applications has long been associated with unacceptable particulate wear and metallic debris. Additionally, the anterior, top and posterior surface portions of hinge post 106 do not come into contact with any portion of the femoral component 10 due to the presence of large clearance space.

In contrast the present invention utilizes hinge post 174 (see Figures 30a thru 30e) as a principal articular bearing member to (a) significantly compliment the femoro-tibial bearing contact area to sustain joint load, to decelerate the femoro-tibial joint motion during extension to reduce impact loading at zero degrees, to significantly sustain side-loads throughout the full flexion range and to stabilize the natural-like multiaxis motion - throughout the full flexion range.

In summary, there are significant differences in the structure and operation of the prosthesis of Forte et al. '021 and that of the present invention, to rebut the application of this reference to either anticipate or render obvious the present invention particularly as claimed. Accordingly, withdrawal of the rejection based on Forte et al. '021 is believed to be in order and is requested.

Claims 44, 49 and 55-56 are rejected under 53 U.S.C. § 103 as unpatentable over Forte et al. '021, in view of Walker, U.S. Patent No. 3,837,009. As this rejection may pertain to the claims particularly as amended, it is traversed.

The deficiencies of Forte et al. '021 have been discussed above and this discussion is incorporated herein and made a part hereof.

The use of a hinge passageway in the form of a slot (slotted hinge port) is not obvious in the above referenced Forte et al. '021; since, the hinge knee prosthesis invention does not translate anteriorly-posteriorly in a natural-like manner, during flexion-extension motion. The Forte et al. '021 prosthesis is a conventional "fixed fulcrum" design, which only allows the femoro-tibial motion to articulate relative to a fixed center of rotationhinge passage, and therefore, not only is no slotted hinge passage required, but there is no suggestion to modify the referenced construction to incorporate such a passage.

The Examiner states "that Forte et al also provide(s) for laxity in the joint kinematics (e.g. column 7, lines 34-40)", in support of the contention that Forte et al. '021 may be modified by the inclusion of a slotted passageway. However, the portion of the patent cited by the Examiner refers to axial rotation, relative to the longitudinal axis of the knee, between the UHMWPE tibial plateau component 12 and metallic tibial sleeve tray component 14. It solely relates, therefore, to knee joint laxity in axial rotation - which is characteristic of the conventional "rotating platform" tibial component design utilized - and does not relate to anterior-posterior femoro-tibial translation kinematics, during flexion.

Walker fails to cure the deficiencies of Forte et al. '021. The Walker Patent describes a hinged knee prosthesis with <u>limited</u> anterior-posterior translation during flexion-extension motion. The hinge pin 20 is positioned within a <u>vertically</u> oriented slotted opening 40, which is distally divergent to provide variable hinge pin clearance with knee flexion, e.g. larger clearance at full flexion (pin position at bottom of slot) and minimal clearance at zero degrees flexion (pin position at top of slot). The greater clearance at full flexion is in response to providing greater (axial) femoro-tibial rotational laxity at full flexion and little-to-zero axial rotational capability at zero flexion - in response to the biomechanical findings by Fike for the <u>normal</u> <u>knee</u>.

With the Walker knee slight anterior-posterior femoro-tibial translation occurs during flexion-extension, due to the mutli-radius kinematics of the femoral condyles 22. The extent of the femoro-tibial translation is very small and in the limit equals the amount of <u>side-clearance</u>, between the hinge pin 20 and vertical slot 40 at full flexion. The maximum value of the anterior-posterior translation, therefore, occurs at maximum flexion and equals one-half the difference between the major diameter (d) of the vertical slot 40 and outside diameter (A) of hinge pin 20. To one of ordinary skill in the art it would appear, based upon the dimensional scale of Figures 5 and 6 of the Walker Patent, that the magnitude of anterior-posterior translation of the Walker knee prosthesis at maximum flexion is only the order of 1mm or so. This capability falls short, compared to conventional resurfacing types of total knee prostheses, compared to the present invention and compared to the natural knee joint; where, the extent of anterior-posterior

translation during posterior roll-back ranges from about 6 to 9mm, depending upon component sizing.

The vertical orientation of the divergent slot 40 of the Walker knee prosthesis significantly restricts the attainment of near-natural knee biomechanics by limiting the anterior-posterior translation with flexion angle. The use of a horizontally oriented hinge pin slot, as taught by the present invention, provides significantly greater natural-like anterior-posterior translation, as a function of flexion angle, by providing a pin-to-slot design which matches the femoro-tibial travel provided by the medial and lateral condylar cam/follower members. This apparently was not obvious to Walker, since the extent of anterior-posterior translation provided by the small slot/pin clearance at full flexion was significantly less than the full kinematic translation potential, afforded by the multiradius design of femoral condyles (20). This resulted in partial constrainment of the anterior-posterior translational motion, resulting in mostly sliding with minimal rolling. Larger clearances from the use of a horizontal slot would have resulted in more efficient mode of femoro-tibial bearing translational articulation, e.g. more rolling and less sliding.

The Examiner also contends that the advantages stated in column 9, lines 49-59 of the Walker Patent would have motivated one with ordinary skill to have designed the hinge pin s lot from a vertical orientation to a horizontal orientation, as used in the present invention. The primary advantage stated by Walker in the passages cited by the Examiner, relates to (axial) rotation freedom of the knee prosthesis, as a function of knee flexion. The vertically oriented divergent hinge pin slot 40 provides proportionally increasing clearance, relative to the traversing hinge pin 20, which allows minimal

rotational freedom at zero degrees flexion and maximum rotational freedom at maximum flexion in a manner, which mimics the normal knee. Walker also indicates that his hinged knee invention also "affords anterior-posterior laxity, which is also characteristic of the anatomical knee joint". As stated above the extent of anterior-posterior translation of the Walker knee invention is limited, relative to anatomical levels, due to small variable side-clearances between the hinge pin slot 40 and hinge pin 20. In a subsequent passage of the Walker Patent it is stated "...the prosthesis restores stability by controlling and limiting lateral, rotational and anterior-posterior laxity". Therefore, Walker admits that anterior-posterior laxity of the knee is limited for stability considerations.

In the present invention anterior-posterior laxity (translation) is not limited but is purposefully extended in order to approximate anatomical levels. Additionally, knee stability is not compromised in the present invention, due to the inherent stability of the various (synchronized) articular bearing surface means, e.g. the outboard medial and lateral condylar cam/follow mechanism means (Figures 28a-28e), the inboard medial and lateral femoro-tibial joint means (Figures 29a-29e) and the intercondylar articular bearing surfaces consisting of the hinge pin/slotted hole and central cam/follower mechanism means (Figures 30a-30e).

To summarize, the Walker patent teaches that a hinged prosthesis having limited translational capability may be constructed which, however, importantly lacks the capability for natural posterior femoro-tibial rollback (see Walker, column 3, lines 39-45) that would provide to the patient the flexibility conferred by the anatomical knee joint, which flexibility is conferred by the hinged prosthesis of the present invention.

Moreover, there is no suggestion anywhere to modify the teachings of Forte et al. '021 to include the teachings of Walker. Even assuming *arguendo* that such a combination were attempted, one would still be left with a prosthesis that lacks the ability to provide to the patient the rolling and sliding movement between the surfaces of the femoral and tibial components, and the extent and sequence of translational movement and posterior rollback that replicates the natural knee joint, and that is achieved by the prosthesis of the claimed invention.

Accordingly, withdrawal of the rejection based on Forte et al. '021 in view of Walker is believed to be in order and is requested.

Claims 41-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The above rejection is believed to be overcome by the amendments to the claims set forth above, and withdrawal of the rejection is therefore requested.

The citation of Hillberry et al. is noted and Applicant agrees that the reference is inapplicable in rejection of the claims, particularly as amended herein.

To summarize, the Claims have been amended to emphasize the distinctions that have been set forth in the application as filed, in the features of the present prosthesis that confer joint performance corresponding to the anatomical knee joint. None of the references of record recognize the need for rolling and sliding motion and translational movement between the respective articular surfaces during knee flexion, and consequently, none suggested means for the achievement of this capability in their

designs. Only the present applicant has identified this need and responded favorably to it by the invention disclosed and claimed herein.

In view of the above and foregoing, reconsideration and withdrawal of the outstanding grounds of rejection and early allowance of the claims as amended are believed to be in order and are courteously solicited.

Respectfully submitted,

DAVID A. JACKSON
Attorney for Applicant
Registration No. 26,742

KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack, NJ 07601
(201) 487-5800